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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,266	10/13/2005	Samuel I Stupp	NANO 107 US2 (NU 22092)	1005
62249	7590	11/07/2007	EXAMINER	
BENET GROUP LLC C/O INTELLEVATE P.O. BOX 52050 MINNEAPOLIS, MN 55402			LUKTON, DAVID	
			ART UNIT	PAPER NUMBER
			1654	
			MAIL DATE	DELIVERY MODE
			11/07/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/534,266

Applicant(s)

STUPP ET AL.

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 2-5, 11-16, 18-21 and 27-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 6-10, 17 and 22-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

Pursuant to the response filed 8/27/07, claims 1, 6, 17, 22 have been amended. Claims 2, 11-16, 18, 27-36 are withdrawn, as in the previous Office action. In addition, claim 5 is withdrawn. Claim 1 requires one lyophilic group to be peptidic, and the other to be non-peptidic. Claim 5, by virtue of its dependence on claim 1, requires both groups to be non-peptidic. Claims 1, 6-10, 17, 22-26 are examined in this Office action.

Applicants' arguments filed 8/27/07 have been considered and found persuasive in part. The rejection of claims 1, 5, 17, 19, 21 as anticipated by Kogiso (*BBRC*, 2000) is withdrawn. Also withdrawn is the rejection of claims 1, 5, 17, 21 as unpatentable over Knudsen ('924).



The following is a quotation of the first paragraph of 35 U.S.C. §112:

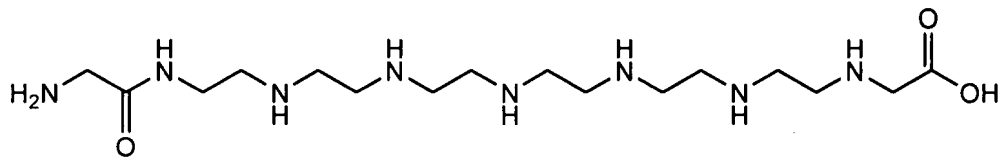
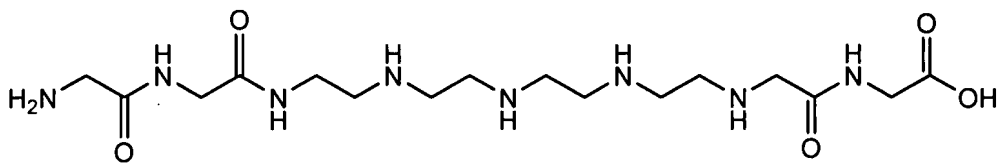
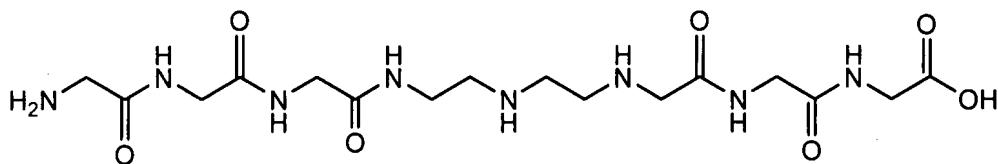
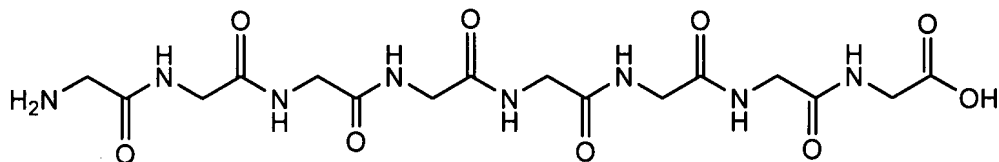
The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6-9, 17, 22-25 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

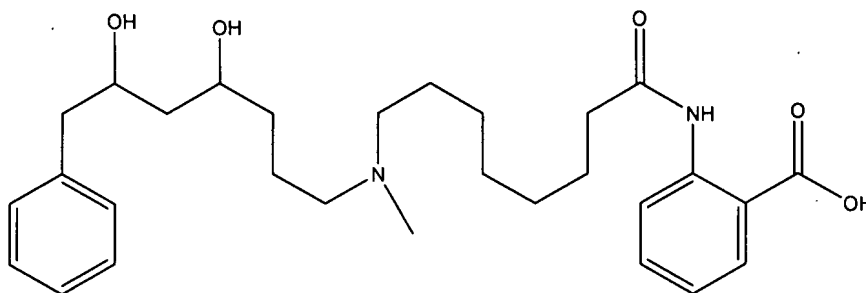
Claim 1 recites the term "peptidic" and "non-peptidic". It is stipulated that the peptide chemist of ordinary skill would have previously encountered the term "peptidic".

The issue, however, is exactly what is meant by this, and equally important, where the line is drawn between a compound that is "peptidic" and one that is "non-peptidic".

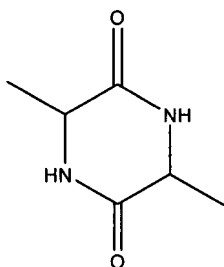
Consider the following four compounds:



The first of these is clearly a peptide (glycine is used just for simplicity). By some accounts, the second compound would qualify as a peptide as well. Clearly, the fourth compound is not a peptide. As for the third compound, most would argue that it does not qualify as a peptide either. In any case, there would be no agreement as to the dividing line between what qualifies as "peptidic" and "non-peptidic" in this series. Consider next the following compound:



Is this "peptidic" or is it "non-peptidic"...? One could argue that it is "peptidic", since it does actually contain two amino acids that are bonded together in amide linkage. But many others would argue that it does not really qualify. Finally, consider the following compound:



This compound is readily obtained by cyclizing the dipeptide alaninyl-alanine. But does it qualify as a peptide?

Thus, there is no descriptive support for the two terms at issue, and there is no agreement among peptide chemists of ordinary skill as to the dividing line between the two terms at issue.



Claims 1 and 17 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a composition. A "composition", however, must have at least two components, otherwise it is a compound. If one has a single, pure compound, one is not in possession of a composition. Thus, claim 1 effectively mandates the presence of a second compound or material, yet is silent as to what that might be. The same issue applies in the case of claim 17. In response, applicants have argued that the term "composition" is accepted in claims. Certainly it is true that there are countless patent claims which contain the term "composition". But that does not mean that all claims which recite this term are definite in their meaning. Applicants have also argued that the term provides for the existence of additional components. This particular assertion is misleading, if not accurate. That is so, because rather than merely permitting the existence of additional components, the term (as used in claim 1) mandates the presence of additional components; at the same time, the claim provides no

clues as to what those additional components might be. (The same applies in the case of claim 17).



The following is a quotation of 35 USC, §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made. Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

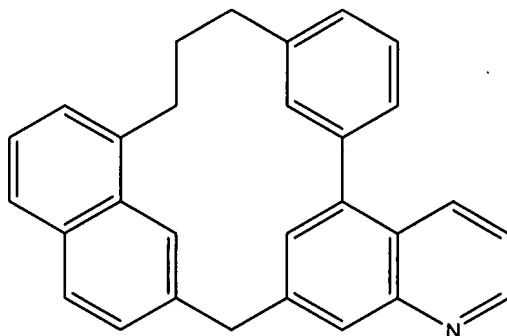
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1, 6-10, 22, 26 are rejected under 35 U.S.C. §103 as being unpatentable over Darcy (US 2003/0092672).

As indicated previously, Darcy discloses bola amphiphiles which form micelles. In response applicants have argued that the disclosed bola amphiphiles are cyclic. Applicants have further argued that it is impossible for any component of a cyclic structure to have an "end" (as the term "end" is used in the instant claims). The examiner disagrees. Consider a simple circle (or more accurately, an oval):

O

It is true that for a circle (or oval), there is no “beginning” or “end”. But the analysis does not end there. Consider the following compound (randomly selected for purposes of illustration):



This is a cyclic molecule, wherein the ring contains a phenyl group, a naphthyl group, and a quinolinyl group. As it happens, the naphthyl group is a group that has a “first end” and a “second end”, and the quinolinyl group also has a “first end” and a “second end”. Even the phenyl group could be viewed as having two “ends”, each corresponding to the



point of attachment. And certainly the propylene group has two ends. All of the foregoing is true, despite the fact that the compound is cyclic. Possible one could make the argument that the molecule overall does not have two ends, but regardless of where one stands on this particular question, the fact is that components of the cyclic structure (e.g., the propylene group or the naphthalene group) have two "ends". An analysis similar to the foregoing applies to the Darcy compounds. While one could possibly make the argument that the disclosed molecules overall do not have two ends, the fact is that substructures within the overall molecules (of Darcy ) do. As it happens, the instant claims do not exclude cyclic structures. The rejection is maintained.



THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

- Reference B1 was stricken from the IDS because of the absence of a translation. The record should be made clear that only the abstract was considered. It is suggested that applicants submit an IDS with the following recited:

**Abstract of** Shimizu, T., JP 403099096, issued April, 1991

- The PCT applications have been stricken from the IDS because they have not been received.
- Reference C45 has been stricken from the IDS because it was not received.
- Reference A36 has been stricken because it is not a U.S. Patent. A section labeled "other documents" could be created. Alternatively the corresponding PG Pub document can be cited.
- Reference C319 has been stricken because insufficient information has been provided to uniquely identify the document. In addition, the reference has not been received.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON, PH.D.  
PRIMARY EXAMINER